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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,392	01/13/2006	Stephan Soyka	65084.000012	2846

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EXAMINER	
PAGE, BRENT T	

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1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,392	SOYKA ET AL.	
	Examiner	Art Unit	
	BRENT PAGE	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8-14 and 16-22* is/are pending in the application.

4a) Of the above claim(s) *16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 8-14 and 17-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Reply filed by Applicants on 02/03/2010 is hereby acknowledged. Claims 1-5, 8-14 and 16-22 are pending. Claim 16 is withdrawn. Claims 5, 8-14 and 17-22 are examined herein on the merits.

Specification

The objection to the specification is hereby withdrawn in response to the amendments made to the specification removing the hyperlinks from the specification.

Claim Rejections - 35 USC § 112-1st paragraph

Claims 1-5, 10-14, and 17-22 are rejected and claim 8 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims are rejected for the reasons applied to claims 6-8 in the previous office action mailed out on 08/04/2009, as well as the reasons set forth below.

The claims are drawn to multitudes of unspecified genetic modifications and foreign nucleic acids that would lead to a reduction in the "activity" of the R1 protein.

In contrast the specification only describes the use of sequences from the R1 gene itself for reducing the expression of the R1 gene. There are literally thousands of genes that could potentially affect the expression of the R1 gene. The specification does not contain working examples of genes other than the R1 gene that could be

disrupted, modified or transformed into the plant that would reduce the expression of the R1 gene. The specification also does not describe which structural features or enzymatic properties would need to be present in genes other than R1 in order for the reduction in R1 to result from their inclusion as a foreign nucleic acid molecule.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a

functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Response to Arguments

Applicant's arguments filed 02/03/2010 have been fully considered but they are not persuasive.

Applicants urge that methods for reducing the activity of R1 proteins are known in the art and therefore the scope of the claims as written is adequately described (see pages 7-8 of resposne).

This is not persuasive because the specification points out specifically, that it is "of particular importance that inhibiting the expression of the potato R1 gene in transgenic potato plants or their tubers leads to a reduction of what is termed cold-induced sweetenings" (see page 15, 1st paragraph of instant specification). Only molecules based on the sequence of the R1 gene or designed to disrupt the R1 gene have been described as useful for this invention. The R1 gene phosphorylates starch and many other enzymes of this biosynthetic pathway would be expected to lead to a reduction in activity of the R1 proteins, particularly wherein the "activity" could mean less substrate for the R1 protein rather than the one mode of reducing the expression of the R1 gene as taught in the specification. The incorporation of the limitations involving the reduction of the R1 protein in claims 1 and 12 have resulted in the rejection applying to claims 1-5, 10-14 and 17-22.

Applicants urge that the claimed invention is not the reduction of R1 activity per se, but rather the finding that plants with reduced soluble sugars permits the production of foods with reduced acrylamide content (see pages 8-9 of response).

This is not persuasive because the specification does not describe a reduction in activity of R1 leading to reduced soluble content without altering the gene that encodes the R1 protein or without inhibiting the expression of R1. The claims are not drawn to plants with inhibited R1 expression, but rather plants with a reduced R1 "activity". The breadth of the claims encompass literally any genetic modification that might result in a reduced activity of R1 activity including genetic alterations applying to a multitude of

genes that are not the R1 gene, not limited to but including transcription factors that would affect a multitude of genes.

Claim Rejections - 35 USC § 112-2nd paragraph

Applicant's arguments, see page 9 of response, filed 02/03/2010, with respect to lack of antecedent basis have been fully considered and are persuasive when taken together with the claim amendments. The rejection of claim 17 under 35 USC 112 2nd paragraph as being indefinite has been withdrawn.

Claim Rejections - 35 USC § 103

Applicant's arguments, see page 9 of response, filed 02/03/2010, with respect to the claims being obvious over Sonnewald in view of Walsh have been fully considered and are persuasive when taken together with the claim amendments incorporating the limitations of reduced R1 protein activity. The rejection of claims 1-5, 10-14 and 17-18 under 35 USC 103 as being obvious over Sonnewald in view of Walsh has been withdrawn.

Claims 1-5, 8-14 and 17-18 remain rejected and claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sonnewald (US20020019998) in view of Frohberg (US Patent 6521816, filed 11/09/1999) and further, in view of Walsh et al (WO9740707).

The claims are drawn to a process for reducing acrylamide content of heat-treated foods comprising selecting plant material with a reduced content of soluble sugars compared to conventional plant material, processing plant material and heat treating the food, wherein the acrylamide content is reduced by at least 15%, at least 30%, and wherein the heat treatment is carried out at temperatures of at least 100 degrees Celsius, wherein the foods include potato chips, french fries, or parfried potato chips, wherein the plant material is genetically modified to reduce the activity of the R1 protein, and wherein the plant material orginates from potato.

Sonnewald teaches the genetic modification of potato plants by reducing the expression of the sucrose-phosphate synthase gene (SPS) by anti-sense constructs (see claims Examples 3 and 4, for example) and specifically teaches that the utility of a such an invention is the reduction in soluble sugars that lead to negative effects due to the Maillard reaction for preparing fries and crips from potato (see paragraph 11 of the specification, for example).

Sonnewald does not specifically teach the heat treatment of the resulting potato plants for the production of food or the reduction in acrylamide content.

Walsh et al teach the heat-treatment of potato crisps for the production of food, wherein the temperatures are above 100 degrees Celsius (see claim 1 wherein the range of temperature is 132-196 degrees Celsius, for example).

Frohberg teaches the transformation of potato plants with a vector comprising DNA encoding the R1 protein wherein the expression of R1 is reduced relative to non transformed plants (see claims 1-8 and 22-23, for example) and that cold sweetening

leads to the reduction in sugars in the resulting plant material (see 4th paragraph under Background of invention, for example).

Given the state of the art and the disclosures by Sonnewald, Frohberg and Walsh et al, it would have been obvious to one of ordinary skill in the art to select the plant material of the transgenic plants taught by Frohberg to produce the par-fried potato strips in the method taught by Walsh et al to avoid the deleterious effects of the Maillard reaction as taught by and evidenced by Sonnewald above. One would have been motivated to do so based on the disclosure by Sonnewald. The specific reductions in acrylamide content would naturally follow from the reduced amount of sugar taught by Frohberg.

Response to Arguments

Applicant's arguments filed 02/03/2010 have been fully considered but they are not persuasive.

Applicants urge that Sonnewald and Walsh alone or in combination fail to teach or suggest reducing the activity of one or more endogenous R1 proteins (see page 10 of response).

This is not persuasive because Sonnewald and Walsh are not relied on to provide the teaching of reducing the activity of R1 proteins. Frohberg is cited and teach the reduction of R1 protein activity using essentially the same transgenic methods of the instant invention. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642

F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants urge that Frohberg does not teach that reducing R1 protein activity reduces cold-sweetening or sugar content (see pages 10-11 of response).

Firstly, Frohberg states “Moreover, there is some interest in producing modified starches which would render plant cells and plant organs containing this starch more suitable for further processing, such as for the production of popcorn or corn flakes from maize or of French fries, crisps or potato powder from potatoes. There is a particular interest in improving the starches in such a way, that they show a reduced "cold sweetening", i.e. a decreased release of reduced sugars (especially glucose) during long-term storage at low temperatures" and “Therefore, the problem underlying the present invention is to provide nucleic acid molecules and methods which allow for the alteration of plants in such a way, that they synthesize a starch which differs from starch naturally synthesized in plants with respect to its physical and/or chemical properties (these properties in turn influence, for example, the cooking properties and/or the nutritional value of the harvestable parts of these plants) and which starch is therefore more suitable for general and/or particular uses. This problem is solved by the provision of the embodiments described in the claims.” (see paragraphs 4 and 7-8 of background of invention). These statements suggest that, contrary to Applicants assertion, that the modulation of the activity of the R1 protein does, in fact, lead to a reduced cold-sweetening simply taking the statements of Frohberg at face value. No evidence by Frohberg or otherwise has been presented to suggest that Frohberg was

unaware of this property of the R1 protein, particularly given the aim of the invention and the statement that the invention satisfies this aim, as recited above.

Furthermore, as to the motivation to combine the references, the teaching by Sonnewald that reduced soluble sugar content decreases the subtstrate for the Malliard reaction is sufficient motivation, particularly in light of the statements above, by Frohberg, to use plants with reduced R1 activity as suggested by Frohberg for methods involving heat treatment particularly potato crisps.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

/Anne Marie Grunberg/
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